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No. 04-1047

IN THE
Supreme Court of the United States

WARNER-LAMBERT CO., *et al.*,
Petitioners,

v.

MARY ROSE WAKEFIELD,
Respondent.

On Petition for a Writ of Certiorari to the Oklahoma Court of Civil Appeals

MOTION FOR LEAVE TO FILE AND BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONERS

BRUCE N. KUHLIK
MARJORIE E. POWELL
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
1100 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 835-3400

DANIEL E. TROY*
COLEEN KLASMEIER
ERIC A. SHUMSKY
SIDLEY AUSTIN BROWN & WOOD LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8496

Counsel for Amicus Curiae

* Counsel of Record

April 4, 2005

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MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Pursuant to Rule 37.2 of the Rules of this Court, Pharmaceutical Research and Manufacturers of America (PhRMA) requests leave to file the accompanying brief as *amicus curiae* in support of Petitioners. Petitioners have consented to the filing of this brief. Counsel for Respondent Wakefield did not respond to multiple requests for consent.

PhRMA is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA member companies produce the vast majority of the prescription medicines used in the United States, and invested an estimated $38.8 billion in discovering and developing new medicines in 2004. This substantial private research effort is the source of virtually all new drugs marketed in the United States.

The issues presented are of fundamental importance to the pharmaceutical industry, because the imposition of massive punitive damages threatens particularly grave consequences for this industry, and for public health generally. Pharmaceuticals are approved by the Food and Drug Administration and marketed nationwide (and, as in this case, globally), so a rule that permits punitive damages to be imposed on the basis of global revenues for drug sales threatens to impose particularly heavy and unwarranted burdens on the pharmaceutical industry. This is all the more true because the discovery and development of new drugs is such an expensive, time-consuming and risky process. It takes up to 15 years, and close to 10,000 failures, for every one success in developing a new drug. Even then, only three out of every 10 medicines brought to market generate enough revenue to cover the average out-of-pocket costs of researching and developing a new medicine. The imposition of punitive damages like those at issue here, which are constitutionally excessive and have no nexus to the place of the alleged injury, threatens to stifle innovation in the pharmaceutical industry and to lessen the availability of pharmaceuticals, all to the detriment of public health.

Respectfully submitted,

BRUCE N. KUHLIK
MARJORIE E. POWELL
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
1100 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 835-3400

DANIEL E. TROY*
COLEEN KLASMEIER
ERIC A. SHUMSKY
SIDLEY AUSTIN BROWN & WOOD LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8496

Counsel for Amicus Curiae

* Counsel of Record

April 4, 2005

QUESTIONS PRESENTED

1. Whether a punitive damages award, which was based on worldwide gross sales of an FDA-approved prescription drug, conflicted with *State Farm Mutual Automobile Insurance Co.* v. *Campbell*, 538 U.S. 408, 422 (2003), and *BMW of North America, Inc.* v. *Gore*, 517 U.S. 559 (1996), which prohibit the imposition of punitive damages on the basis of lawful out-of-state conduct.

2. Whether a $10 million punitive damages award was grossly excessive under *State Farm* and *BMW*, given that compensatory damages were $1.55 million, and that under *State Farm*, where "compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee."

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INTEREST OF *AMICUS CURIAE*[1]

The interest of *amicus curiae* is set forth in the accompanying motion for leave to file this brief.

SUMMARY OF ARGUMENT

The court below permitted punitive damages to be awarded based on Warner-Lambert's *global* sales of a lawful, FDA-approved drug, despite the fact that Wakefield put on no evidence that Warner-Lambert made any illegal sale of the drug in *any* jurisdiction, foreign or domestic, outside of the forum State. The decision below directly contravenes this Court's holdings in *State Farm Mutual Automobile Insurance Co.* v. *Campbell*, 538 U.S. 408 (2003), and *BMW of North America, Inc.* v. *Gore*, 517 U.S. 559 (1996), concerning the unavailability of punitive damages for out-of-state conduct. Moreover, the award of $10 million in punitive damages, despite an already "substantial" compensatory award of $1.55 million, 538 U.S. at 425, is flatly incompatible with the Court's guidance about the proper ratio between punitive and compensatory damages.

The possibility of unconstitutionally excessive punitive damages awards against drug manufacturers threatens to discourage medical research and, in the absence of this Court's intervention, to inhibit Americans' access to significant and beneficial pharmaceutical therapies. Properly applied, the due process limitations on punitive damages awards elucidated in *BMW* and *State Farm* would prevent the imposition of standardless punitive damages that have long threatened the pharmaceutical industry.

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[1] Pursuant to Rule 37.6, PhRMA states that no counsel for a party authored this brief in whole or in part, and no person or entity, other than PhRMA or its members, made a monetary contribution to the preparation or submission of this brief. A list of PhRMA's members is available at http://www.phrma.org/whoweare/members.

Excessive punitive damages awards such as this one spawn grave consequences for public health. As PhRMA demonstrates in this brief, such excessive tort liability, as well as the fear of such liability, have discouraged research and development and have diminished the availability of beneficial products to those who need them. These adverse developments have impaired physicians' access to important and often unique pharmaceutical therapies, and have thereby interfered with doctors' ability to provide the highest quality medical care to their patients.

Punitive damages particularly compromise the development and distribution of new drugs. Pharmaceutical research and development are unusually expensive, time-consuming tasks. Despite extensive testing and exacting federal regulation, full knowledge of the risks presented by a new drug can never be gained before marketing. And all drugs are associated with adverse events in some patients. These harms cannot be avoided, regardless of the degree of care exercised by the manufacturer and the prescriber. FDA's goal, therefore, is not to eliminate all risk from new medicines; to do so would be counterproductive, harming public health by needlessly limiting public access to beneficial drugs. Rather, FDA's purpose is to ensure that these inevitable risks are appropriate in light of the expected benefits. When FDA has made such a determination, as it did here in approving Rezulin, the imposition of punitive damages at all—much less punitive damages of the unconstitutional magnitude awarded here—is unjustifiable. Under such circumstances, it is simply implausible to claim that a drug manufacturer has acted with malice such that punitive damages are appropriate. This Court should grant review to prevent the significant harm to public health that the decision below, and others like it, are likely to cause.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW SQUARELY CONFLICTS WITH *STATE FARM* AND *BMW*.

This Court's decisions in *State Farm* and *BMW* recognized clear due process limitations on the permissible bases for, and scope of, punitive damages awards. The decision below disregards those limits. Although the Petition ably sets forth this important conflict, the errors below cannot go unremarked here both because of their severity, and because these errors take on heightened importance in the pharmaceutical context, see *infra* Sections II, III.

1. First and foremost, in upholding a punitive damages award premised on not just *national*, but *international* sales of the FDA-approved drug Rezulin, the court below contravened *State Farm* and *BMW*. Both *State Farm* and *BMW* evaluated punitive damages awards based, at least in part, on lawful out-of-state conduct. And in both cases, this Court made clear that such conduct cannot form the basis of a punitive damages award:

> A State cannot punish a defendant for conduct that may have been lawful where it occurred. Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction.

State Farm, 538 U.S. at 421 (citations omitted); accord *BMW*, 517 U.S. at 572. Furthermore, it is rarely if ever appropriate for one State to punish even *un*lawful extraterritorial conduct. See, *e.g.*, *BMW*, 517 U.S. at 585 (a State may not "use the punitive damages deterrent as a means of imposing its regulatory policies on the entire Nation"); *Huntington* v. *Attrill*, 146 U.S. 657, 669 (1892) ("Laws have no force of themselves beyond the jurisdiction of the state which enacts them, and can have extraterritorial effect only by the comity of other states."). Even if a State could punish unlawful extraterrito-

rial conduct, the determination of unlawfulness must normally be based upon the laws of the foreign State. *State Farm*, 538 U.S. at 421-22.

The punitive damages award in this case is flatly inconsistent with the rule of *State Farm* and *BMW*. It rests on an Oklahoma statute permitting punitive damages to be awarded based on "the increased financial benefit derived by the defendant ... as a direct result of the conduct causing the injury to the plaintiff *and other persons or entities*," Okla. Stat. tit. 23, § 9.1(C)(2)(c) (emphasis added), regardless of the geographic location of those other people and regardless whether the conduct was lawful where it occurred.[2] Wakefield argued that "financial benefit" under this statute should be based upon the profit Warner-Lambert derived from worldwide sales of Rezulin during the period she took the drug. See Pet. 13. And that is what the court below understood to have been the basis for the punitive damages award. Pet. App. 16-17.

Thus, the punitive damages were predicated upon innumerable out-of-state actions involving countless out-of-state parties—namely, sales of Rezulin in States other than Oklahoma, and countries other than the United States. But at no point did Wakefield present evidence that Warner-Lambert's conduct in any such jurisdiction was unlawful. Wakefield did not even seek to apply the law of any other jurisdiction, as *State Farm* would require. 538 U.S. at 421-22.[3] And all of these

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[2] There are other provisions of Oklahoma law upon which the punitive damages award could theoretically have been based, *see generally* Okla. Stat. tit. 23, § 9.1, but none would justify an award of this magnitude. The court below took it as a given that subsection (C)(2)(c) was at issue. Pet. App. 16-17, 23.

[3] Nor would it be sufficient for Wakefield to claim that Warner-Lambert's conduct *might* have been unlawful in some other jurisdictions. Even leaving aside this Court's strong indication that unlawful out-of-state conduct is rarely if ever actionable, *State Farm*, 538 U.S. at 421; *BMW*, 517 U.S. at 585, *BMW* makes plain that a plaintiff seeking to impose punitive damages on this basis bears the burden of showing that the "out-of-state conduct was unlawful," 517 U.S. at 573. Indeed, Warner-Lambert's

errors were compounded by the use of Warner-Lambert's gross revenues, rather than merely its profits, in calculating punitive damages. Pet. 11. In short, *State Farm*'s requirements were unmet.

Not only did Wakefield fail to prove that these extraterritorial sales violated the law. In addition, she failed to present proof that would make the evidence of worldwide sales even *relevant*. *State Farm* held that "[l]awful out-of-state conduct may be probative," even when not directly relevant to a punitive damages calculation, "when it demonstrates the deliberateness and culpability of the defendant's action in the State where it is tortious." 538 U.S. at 422. But for proof to be used even for that limited purpose, the defendant's "conduct must have a nexus to the specific harm suffered by the plaintiff." *Id.* Here, there is no evidence at all demonstrating such a "nexus," nor could there be—there is no conceivable nexus between lawful, worldwide sales of Rezulin and the harm purportedly suffered by Wakefield. The court below erred, in direct contravention of this Court's precedents, in failing to require such proof.

Indeed, the refusal of the trial court to properly instruct the jury on this issue itself conflicts with *State Farm*. In *State Farm*, the Court held that "[a] jury *must* be instructed ... that it may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the jurisdiction where it occurred." 538 U.S. at 422 (emphasis added). Yet the trial court refused to instruct the jury that it could not punish the defendant for extraterritorial conduct. Indeed, it overruled objections on this same basis. Pet. App. 6, 16-17. This obvious mistake requires correction by the Court, lest other courts, in Oklahoma and elsewhere, follow this same approach.

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conduct almost certainly was lawful in certain other States—such as, for instance, Michigan, where FDA approval forecloses state-law tort liability. *See* Mich. Comp. Laws § 600.2946(5).

2. Certiorari is further warranted because the decision below disregards limits on the proper ratio between punitive and compensatory damages set forth in *State Farm* and *BMW*. Although the Court has said that there is no "bright-line ratio which a punitive damages award cannot exceed," *State Farm*, 538 U.S. at 425, it has also given the lower courts significant guidance about appropriate ratios. The Court has repeatedly indicated that a 4-to-1 ratio "might be close to the line of constitutional impropriety," *id.* (citing *Pacific Mut. Life Ins. Co.* v. *Haslip*, 499 U.S. 1, 23-24 (1991), and *BMW*, 517 U.S. at 581), and "referenced a long legislative history, dating back over 700 years and going forward to today, providing for sanctions of double, treble, or quadruple damages to deter and punish," *id.* Moreover, "[w]hen compensatory damages are substantial, then a ... ratio[] perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *Id.*

In *State Farm*, the award of $1 million was held to be "substantial." *Id.* at 426. The Court accordingly held that the *Gore* guideposts "likely would justify a punitive damages award at or near the amount of compensatory damages." *Id.* at 429. The award of $1.55 million in this case is, *a fortiori*, "substantial." The proper ratio is likewise "at or near the amount of compensatory damages." This conclusion is confirmed by the total lack of evidence of reprehensible conduct on the part of Warner-Lambert; on the contrary, all that the company did was to sell a drug—unquestionably beneficial to numerous users—that passed FDA's exacting approval process. See *infra* Section III. Yet the jury awarded punitive damages of $10 million. And instead of vacating the punitive damages award, or at least limiting punitive damages to comport with this Court's precedents, the court below upheld an award over *six times greater* than compensatory damages, without even attempting to justify this result.

The decision below is only the latest to disregard *State Farm* in this fashion. Every passing month brings additional

unconstitutional awards of punitive damages. On remand in *State Farm*, for instance, the Utah Supreme Court ignored this Court's statement that the punitive damages "'likely'" should be "'at or near the amount of compensatory damages'"—approximately $1 million. Instead, it awarded over $9 million in punitive damages. *Campbell* v. *State Farm Mut. Auto. Ins. Co.*, 98 P.3d 409, 410-12 (Utah), *cert. denied*, 125 S. Ct. 114 (2004). The Ninth Circuit likewise has disregarded *State Farm*. It has embraced the remarkable proposition that "*State Farm*'s 1:1 compensatory to punitive damages ratio is not binding, no matter how factually similar the cases may be." *Hangarter* v. *Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1014 (9th Cir. 2004). Other courts have similarly ignored *State Farm*.[4] The Court's review is needed to give force to its precedents.

II. EXCESSIVE PUNITIVE DAMAGES THREATEN PUBLIC HEALTH BY DECREASING INNOVATION AND THE AVAILABILITY OF PHARMACEUTICALS.

The disregard of *State Farm* set forth above and in the Petition takes on particular importance in the context of product liability suits concerning the marketing of pharmaceuticals. Mass tort actions against pharmaceutical manufacturers, in which massive punitive damages are sought, are by now

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[4] *E.g.*, *Eden Elec., Ltd.* v. *Amana Co.*, 370 F.3d 824, 828-29 (8th Cir. 2004) (upholding a punitive damages award of $10 million on the theory that that award was in fact "at or near" the compensatory damage award of $2.4 million), *cert. denied*, 73 U.S.L.W. 3363 (U.S. Feb. 22, 2005); *Rhone-Poulenc Agro, S.A.* v. *DeKalb Genetics Corp.*, 345 F.3d 1366, 1371-72 (Fed. Cir. 2003), *cert. denied*, 540 U.S. 1183 (2004) ($50 million punitive; $15 million compensatory); *Advocat, Inc.* v. *Sauer*, 111 S.W.3d 346, 361, 363 (Ark.), *cert. denied*, 540 U.S. 1004, 1012 (2003) ($21 million; $5 million); *In re the Exxon Valdez*, 296 F. Supp. 2d 1071, 1101, 1110 (D. Alaska 2004) ($4.5 billion; approximately $513 million "total actual harm"); *Interclaim Holdings Ltd.* v. *Ness, Motley, Loadholt, Richardson & Poole*, 298 F. Supp. 2d 746, 748, 765 (N.D. Ill. 2004) ($27.7 million; $8.3 million).

commonplace. Litigation against drug companies has been recognized as a growth industry for some time now. See Terence Dungworth, *Product Liability and the Business Sector* ix (RAND Inst. for Civil Justice 1988) ("no other defendants in any industry have experienced federal litigation growth comparable to that observed in asbestos or single-product pharmaceutical suits"). Over one 13-year period, approximately 11,000 such cases were brought in federal court alone. *Id.* at 38. That trend appears to have continued unabated. Merck, the manufacturer of the painkiller Vioxx, withdrew that product from the market only months ago. Seventy putative class actions have already been filed, in addition to hundreds of individual suits.[5] Wyeth (formerly American Home Products) has paid billions of dollars to litigate and settle claims stemming from voluntary withdrawal of the diet drug combination Fen-Phen—yet still faces lawsuits from more than *60,000* claimants who opted out of the settlement. See Melissa Nann Burke, *Philadelphia Sees 10,000 Fen-Phen Cases in 2004*, Nat'l L.J., Jan. 3, 2005, at 11.

Excessive tort verdicts in general, and punitive damages in particular, have wreaked havoc upon the federally regulated market for these products. Two effects of these suits deserve special mention, because they vividly illustrate the way the current liability environment is harming public health, and they demonstrate the need for this Court's intervention to reaffirm the constitutional limitations it has identified. *First*, such damages appear to stifle innovation in the pharmaceutical industry. Anticipated litigation costs have prevented drug

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[5] *See* Press Release, Merck, Merck Announces Voluntary Worldwide Withdrawal of VIOXX® (Sept. 30, 2004), *available at* http://www.merck.com/newsroom/press_releases/product/2004_0930.html; Susan Todd, *Vioxx Lawsuits To Be Rolled into One*, Newark Star-Ledger, Feb. 17, 2005, *available at* http://www.nj.com /business/ledger/index.ssf?/base/business-0/1108620648702 40.xml; Robert Steyer, *Vioxx Lawsuits Swamp Merck*, The Street.com, Dec. 14, 2004, *available at* http://www.thestreet.com/_googlen/stocks/robertsteyer/10199047.html?cm_ven=GOOGLEN&cm_cat=FREE&cm_ite=NA.

manufacturers from investing in new product development. Specific areas of research (such as vaccines) have been particularly affected. *Second*, excessive tort damages have reduced the availability of drugs. Not only are fewer drugs being researched and created—i.e., the "innovation" effect first noted—but also existing, FDA-approved, beneficial drugs have been removed from the market for fear of liability.

1. *Innovation.* The tort system is "having a profound negative impact on the development of new medical technologies." American Med. Ass'n, Report of the Board of Trustees, Impact of Product Liability on the Development of New Medical Technologies 1 (1988). "Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance." *Id.* As Justice O'Connor recognized some 15 years ago, "The threat of ... enormous [punitive damages] awards has a detrimental effect on the research and development of new products. Some manufacturers of prescription drugs, for example, have decided that it is better to avoid uncertain liability than to introduce a new pill or vaccine into the market." *Browning-Ferris Indus. of Vt., Inc.* v. *Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part).

This unfortunate effect may reflect a rational response to today's irrational liability environment, of which punitive damages are an important part. The choice to research and try to bring a new drug to market involves a calculation of expected benefits and expected costs. Massive tort verdicts can dramatically skew the cost side of that equation. Expenditures on research and development increase when liability costs decrease. See Amy Finkelstein, *Health Policy and Technological Change: Evidence from the Vaccine Industry* 22-24 (Nat'l Bureau of Econ. Research Working Paper No. 9460, 2003), *available at* http://www.nber.org/papers/

w9460.[6] And, where the level of risk is high—as it is in a system in which punitive damages have no reasonable bounds—the risk of liability is inversely related to investment in research and development activity. Michael J. Moore & W. Kip Viscusi, *Product Liability Entering the Twenty-first Century: The U.S. Perspective* 25, 27 (2001).[7]

Excessive liability—and, *a fortiori*, unbounded punitive damages awards of the sort blessed by the court below—has especially pernicious effects on vaccines, a particularly perverse effect in light of those products' unquestioned public health benefits. Am. Med. Ass'n, *supra*, at 6-7. The reason for this effect is simple: "Products with less market potential are more vulnerable to a given degree of liability potential." Steven Garber, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* 167 (1993). And, where vaccines are concerned, "[t]he profit per dose is low,

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[6] Finkelstein's research focused on the Vaccine Injury Compensation Fund (VICF), a no-fault product liability system paid for by excise taxes on certain childhood vaccines. That system took the place of tort remedies stemming from those vaccines, and applied a fixed payment schedule for claims. *See* 42 U.S.C. §§ 300aa-10 to -34; 42 C.F.R. § 100.3. This alternative to the tort system had the salutary effects of reducing risk by normalizing payments and reducing expected liability costs. The result was stark—institution of the Fund led to a statistically significant increase in new clinical trials. Finkelstein, *supra*, at 22-24. Notably, plaintiffs' attorneys have attempted to circumvent the fixed-compensation regime of the VICF by bringing claims for injuries allegedly caused by thimerosal, a preservative used in certain vaccines, rather than by the vaccine itself. *See, e.g.*, *Moss* v. *Merck & Co.*, 381 F.3d 501 (5th Cir. 2004).

[7] *See also* W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Links Between Product Liability and Innovation, in The Liability Maze: The Impact of Liability Law on Safety and Innovation* 81, 107, 114 (Peter W. Huber & Robert E. Litan eds., 1991); W. Kip Viscusi & Michael J. Moore, *Rationalizing the Relationship Between Product Liability and Innovation* ("*Rationalizing*"), *in Tort Law and the Public Interest: Competition, Innovation, and Consumer Welfare* 105, 123 (Peter H. Schuck ed., 1991). Viscusi and Moore's work considers the pharmaceutical sector among other industries, but does not focus exclusively upon it.

and yet the perceived liability per dose is high." John P. Wilson, *The Resolution of Legal Impediments to the Manufacture and Administration of an AIDS Vaccine*, 34 Santa Clara L. Rev. 495, 505 (1994); Viscusi & Moore, *Rationalizing*, at 111.

Thus, the Institute of Medicine has recognized that "apprehensions [about tort liability] act as a deterrent to vaccine production and thereby threaten the public's health." Inst. of Med., *Vaccine Supply and Innovation* 2 (1985); see also U.S. Congress, Office of Tech. Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* 170, 182 (1993). Indeed, "[r]ising liability costs during the 1980s reduced the number of firms producing vaccines for five serious childhood diseases from thirteen in 1981 to three by the end of the decade." Viscusi & Moore, *Rationalizing*, at 111. Concerns about liability have slowed the progress of particular identifiable vaccines, including an AIDS vaccine. See Jon Cohen, *Is Liability Slowing AIDS Vaccines?*, Science, Apr. 10, 1992.[8]

The effect of liability on products with smaller market potential is a particularly timely issue. As science advances, there are greater opportunities for treatments tailored to particular types of individuals, such as patients with a particular genetic makeup, or who fail to respond to existing treatments. Although these treatments promise to be extremely beneficial, they may not generate markets large enough and predictable enough to offset the kinds of liability risks described above.

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[8] The development of contraceptives has similarly been slowed by liability concerns. Experiences like the forced withdrawal of Bendectin as the result of baseless tort suits (described *infra* at 12) have discouraged manufacturers from researching new products indicated for or associated with contraception and pregnancy. *See, e.g.*, Linda Johnson, *Wyeth Won't Resume Norplant Sales*, AP Online, July 26, 2002; Gina Kolata, *Will the Lawyers Kill Off Norplant?*, N.Y. Times, May 28, 1995; *see generally* Inst. of Med. & Nat'l Res. Council, *Developing New Contraceptives: Obstacles and Opportunities* 118-43 (Luigi Mastroianni, Jr. et al. eds., 1990).

2. *Availability*. In addition to discouraging initial product innovation, excessive liability adversely affects public access to beneficial pharmaceuticals by causing the discontinuation of clinical trials, and by forcing already-approved drugs and interested companies from the marketplace. See, *e.g.*, E. Patrick McGuire, The Impact of Product Liability 17 (The Conference Bd., Res. Rpt. No. 908, 1988) (quoting a drug manufacturer: "We have been forced to discontinue sale of therapeutically beneficial drugs because of excessive product liability costs.").

The signal example of market withdrawal concerns Bendectin, a drug approved by FDA for preventing nausea during pregnancy. Starting in 1969, assertions that Bendectin could produce birth defects began to appear in scientific literature. Yet no sound scientific study ever demonstrated a causal relationship between the drug and birth defects, and FDA continued to affirm its safety. Nevertheless, nearly 1700 lawsuits were brought against the manufacturer. Although the company won most cases, in 1983 it withdrew the drug in the United States because its $18 million in annual legal costs and insurance had nearly overtaken its $20 million in annual sales. Marvin E. Jaffe, *Regulation, Litigation, and Innovation in the Pharmaceutical Industry: An Equation for Safety, in Product Liability and Innovation: Managing Risk in an Uncertain Environment* 120, 126 (Janet R. Hunziker & Trevor O. Jonas eds., 1994). As a result, it was reported in 1994 that "treatment for severe nausea during pregnancy now accounts for nearly $40 million of the nation's annual hospital bill." *Id.* Yet "[i]t is unlikely that any new drug will be developed to close this therapeutic gap," *id.*—all this despite the fact that, as FDA reaffirmed in 1999, Bendectin was *not* withdrawn for safety reasons. See Determination That Bendectin Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 64 Fed. Reg. 43190 (Aug. 9, 1999).[9]

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[9] *See generally* Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development, in The Liability Maze: The Impact of Liabil-*

Given the vulnerability of vaccines to liability effects, see *supra* at 9-11 & n.6, it is no surprise that tort liability has diminished the availability of vaccines. Nearly all manufacturers of the diphtheria, pertussis, and tetanus (DTP) vaccine withdrew from the U.S. market due to lawsuits alleging harmful side effects filed in the 1980s. Lasagna, *supra*, at 341-45; see also *supra* at 10-11. In 1987, the CDC announced that the sole manufacturer of a vaccine to prevent Japanese encephalitis would no longer supply the product in the United States because of product liability concerns. Lasagna, *supra*, at 344. And commentators discussing the shortage and then surplus of flu vaccine this past winter have noted that there remain only two manufacturers licensed to sell the flu vaccine in the United States. *E.g.*, Anthony S. Fauci, *A Risky Business*, Wash. Times, Nov. 30, 2004, at A17 (column by the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health). In each of these ways, unbounded punitive damages harm public health, and for all of these reasons, the Court should grant the Petition.[10]

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ity Law on Safety and Innovation 334, 337-41 (Peter W. Huber & Robert E. Litan eds., 1991) (discussing the withdrawal of Bendectin).

[10] In addition, commentators have recognized that product liability, and liability concerns, have been reflected in higher prices. Some of this effect is direct—expected liability costs drive prices up. *See generally* Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & Econ. 203 (1997); Richard L. Manning, *Changing Rules in Tort Law and the Market for Childhood Vaccines*, 37 J.L. & Econ. 247, 258 (1994); Garber, *supra*, at 122; Gina Kolata, *Litigation Causes Huge Price Increase in Childhood Vaccines*, Science, June 13, 1986. There are also indirect effects that contribute to the same result. For instance, manufacturers are driven from the market, which leads to a lack of competition. W. Kip Viscusi, *The Social Costs of Punitive Damages Against Corporations in Environmental and Safety Torts*, 87 Geo. L.J. 285, 326 (1998). These price effects cause further harm to public health.

III. PUNITIVE DAMAGES ARE SINGULARLY INAPPROPRIATE IN LIGHT OF FDA'S STRICT SUPERINTENDENCE OVER PHARMACEUTICALS.

Finally, review is warranted because an award of punitive damages like this one is fundamentally incompatible with—and threatens to undermine—the comprehensive federal regulatory regime that governs new drug approvals. Punitive damages were awarded here on the theory that Warner-Lambert "acted intentionally and with malice toward others," Okla. Stat. tit. 23, § 9.1(C)(1), when it allegedly breached a claimed state-law duty to warn. The finding that Warner-Lambert acted with malice is implausible, given FDA's specific approval of precisely those warnings that formed the basis of the tort award. And the determination of malice is all the more inappropriate in light of the rigorous federal process of review for new drug approvals. That process includes FDA's scientific determination and legal approval of the specific warnings to be provided, and of their adequacy, and it constitutes FDA's conclusion that the drug may be marketed in interstate commerce. A finding of "malice" under such circumstances is gravely erroneous. An award of punitive damages reaching across state lines under such circumstances cries out for this Court's review.

1. The process of developing and obtaining approval to market a new drug is long and expensive. The process takes close to 15 years. Richard J. Findlay, *Originator Drug Development*, 54 Food & Drug L.J. 227, 227 (1999). By 2001, it was estimated to cost an average of $802 million per drug. Press Release, Tufts Ctr. for the Study of Drug Dev., Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at $802 Million (Nov. 30, 2001), *available at* http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6. The last phase of this process is regulatory approval. Under federal law, new drugs must obtain premarket approval from FDA to ensure that they are safe and effective, 21 U.S.C. §§ 355(d), 393(b)(2)(B), and not misbranded,

id. § 331(a), (b). FDA approval requires the submission of a New Drug Application, *id.* § 355(b), which includes reports on investigations for safety and efficacy, *id.* § 355(b)(1)(A), as well as "adequate tests ... to show whether or not [the] drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling," *id.* § 355(d), among other things.

The evaluation of a drug's safety and effectiveness under federal law is inextricably intertwined with its labeling. An applicant seeking approval of a new drug must submit proposed labeling to accompany the product. *Id.* § 355(b)(1)(F). FDA's regulations establish numerous and specific requirements for prescription drug product labeling, 21 C.F.R. pt. 201—including warnings that must reflect known risks based on reliable scientific evidence, *e.g.*, 21 C.F.R. § 201.57(e). The applicant may not deviate from FDA-approved product labeling without receiving supplemental agency approval. *Id.* § 314.70. False or misleading labeling constitutes misbranding, which is prohibited, 21 U.S.C. § 331(a), (b), and is subject to both criminal penalties and civil sanctions, *e.g.*, *id.* §§ 332, 333(a), 334(a).

FDA approved Rezulin, as well as every aspect of its labeling. The drug made its way through the extensive, exhaustive review process mandated by the Federal Food, Drug and Cosmetic Act (FDCA) and by FDA's implementing regulations. FDA determined that Rezulin's labeling was appropriate, and that it contained all necessary warnings. This determination flatly forecloses the claim that Warner-Lambert "acted intentionally and with malice toward others." Okla. Stat. tit. 23, § 9.1(C)(1). Under these circumstances, Warner-Lambert's conduct cannot have been sufficiently wanton to merit punitive damages at all, much less punitive damages of the unconstitutional magnitude awarded here. See *Roginsky* v. *Richardson-Merrell, Inc.*, 378 F.2d 832, 840-41 (2d Cir. 1967) (Friendly, J.) ("A manufacturer distributing a drug to many thousands of users under government regulation

scarcely requires [punitive damages] for manifesting social disapproval and assuring deterrence.").[11]

2. The award of punitive damages under these circumstances appears to be premised on the belief that drugs marketed to consumers can be free of harmful effects. This notion fundamentally misunderstands the nature of pharmaceuticals as well as the FDA approval process. The FDA long has recognized that "[t]here is no such thing as absolute safety in drugs. There are some drugs that are less liable to cause harmful reaction than others, but people die every year from drugs generally regarded as innocuous." Hearings on Drug Safety Before the Subcomm. on Intergovernmental Relations of the House Comm. on Gov't Operations, 88th Cong., pt. 1, at 147 (1964) (testimony of former FDA Commissioner Larrick); see also *Restatement (Second) of Torts* § 402A cmt. k (1965) (recognizing that many drugs are often "unavoidably

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[11] It is no answer to argue, as Wakefield surely will do, that punitive damages are appropriate because (as the court below described the allegation) defendants "downplayed and understated the dangers of the drug in order to obtain approval of the drug by the regulatory [FDA]." Pet. App. 3 (emphasis omitted). This Court has held that "fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law," precisely because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); *id.* at 353 (Stevens, J., concurring).

Nor is it significant that a manufacturer may as a theoretical matter strengthen warnings without seeking FDA's prior approval. 21 C.F.R. § 314.70(c). Manufacturers rarely if ever make any such a change to drug labeling without FDA approval, because if a manufacturer does so and the FDA disagrees with the change, the manufacturer is in violation of the statutory provisions against marketing an unapproved new drug or a misbranded drug. 21 U.S.C. §§ 352, 355(a); *see* Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 Food Drug Cosm. L.J. 233, 236 (1986) ("In actual practice, section 314.70(c) is rarely invoked."). Given that reality, a manufacturer's failure to amend FDA-compliant product labeling to comply with state law cannot be deemed sufficiently wanton to justify punitive damages.

unsafe," even "for their intended and ordinary use") (emphasis omitted).

The FDA approval process cannot, and does not, require that drugs be risk-free: "If the FDA were to demand absolute proof that no short-term or long-term health risks exist, no drug ever would reach the market." Steven R. Salbu, *The FDA and Public Access to New Drugs: Appropriate Levels of Scrutiny in the Wake of HIV, AIDS, and the Diet Drug Debacle*, 79 B.U. L. Rev. 93, 147 (1999). It would be impossible to implement a drug approval process that sought to prevent all adverse reactions, and costly beyond measure to do so. FDA categorizes an adverse reaction as "rare[]" if it occurs in 1 in 1000 cases. 21 C.F.R. § 201.57(g)(2). Yet even studies comprising 3000 patients are unable to identify "uncommon side effects, delayed effects, or consequences of long-term drug administration." Am. Med. Ass'n, *Reporting Adverse Drug and Medical Device Events: Report of the AMA's Council on Ethical and Judicial Affairs*, 49 Food & Drug L.J. 359, 359-60 (1994). Indeed, "to detect the difference between an adverse reaction incidence rate of 1/5000 and 1/10,000, approximately 306,000 patients would have to be observed, which is far more than any study could achieve." *Id.* at 360 (footnote omitted). And to insist upon no adverse reactions as a result of the drug would cause immeasurable harm to public health: "To take the drastic step of forbidding marketing of a drug until all long-term consequences and interactions are identified through formal research would impose unacceptable costs in the form of untreated or inadequately treated illness." *Id.*[12]

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[12] *Accord Vaccine Supply and Innovation*, *supra*, at 8 ("[T]here is no way totally to avoid injuries caused by current vaccines manufactured according to approved procedures and administered in accordance with recommended medical practices short of the total suspension of vaccine use, which is unacceptable because of the increased risk of morbidity and mortality.").

In short, FDA fully contemplates that the drugs it approves will carry some risk. "[S]afety does not mean zero risk." FDA, Report to the FDA Commissioner from the Task Force on Risk Management, Managing the Risks from Medical Product Use 3 (1999), *available at* http://www.fda.gov/oc/tfrm/riskmanagement.pdf. FDA has long acknowledged that its role is to conduct a risk-benefit analysis to determine what risk is *reasonable*. See *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979) ("the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use"); FDA, Managing the Risks from Medical Product Use, *supra*, at 3 ("A safe product is one that has reasonable risks, given the magnitude of the benefit expected and the alternatives available."). As a former Chief Counsel to FDA has explained it, FDA "weighs the drug's therapeutic benefits against the potential risks of its use.... In short, the FDA effectively determines what risks physicians should be permitted to impose upon the patients they treat with therapeutic drugs." Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 9 (1973) (footnote omitted).

This comprehensive regulatory regime is incompatible with multimillion-dollar punitive damages awards, and it certainly forecloses the conclusion that a manufacturer whose drug has been approved pursuant to this process has acted with "malice." When FDA approves a drug, it has exercised its judgment by "weigh[ing] a variety of complicated information and tak[ing] into account a number of ... considerations." FDA, Managing the Risks from Medical Product Use, *supra*, at 30. That the agency has exercised its statutory and regulatory mandate is reason enough for state courts to be precluded from second-guessing the agency's decision. Cf. Administrative Procedure Act, 5 U.S.C. § 706(2)(A); *Chevron U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837 (1984). Warner-Lambert was and is bound by the warning requirements contained in labeling approved by FDA via this regulatory process. Ac-

cordingly, it is simply impossible to conclude that Warner-Lambert acted "intentionally and with malice" by failing to provide additional warnings. To permit state courts to subject Warner-Lambert to punitive damages under such circumstances—much less punitive damages that are squarely foreclosed by this Court's precedents and by constitutional limits—undermines Congress's regulatory scheme, thwarts FDA's authority, and renders every State a mini-regulator of pharmaceuticals. The FDCA and the Constitution foreclose this result.

CONCLUSION

For the foregoing reasons, and those set forth in the Petition, the Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

BRUCE N. KUHLIK
MARJORIE E. POWELL
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
1100 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 835-3400

DANIEL E. TROY*
COLEEN KLASMEIER
ERIC A. SHUMSKY
SIDLEY AUSTIN BROWN & WOOD LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8496

Counsel for Amicus Curiae

* Counsel of Record

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